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Food Safety And Inspection Service
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AUDIT REPORT FOR CROATIA

DECEMBER 4 THROUGH DECEMBER 12, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Republic of Croatia's meat inspection system December 4 through December 12, 2000. Two establishments certified to export meat product to the United States were audited. Both were slaughter and processing establishments.

The last on-site audit of Croatia's inspection system was conducted in November 1999. Two establishments (10 and 139) were on-site audited. Inspection system monitoring and control records, and establishment system documents were also audited. Establishment 10 was acceptable. Establishment 139 was determined marginally acceptable and recommended for re-review by the inspection service. The following deficiencies were cited during the previous audit:

1. Pathogen Reduction (PR). Incorrect use of the incision method evaluation criteria for Sponging method for sampling *Escherichia coli* (*E. coli*) was used, and excision-sampling criteria were being used for evaluation of test results in establishments in both establishments 10 and 139.
2. SSOPs, and performance standards for sanitation, facilities and equipment.
   a) Establishment 139
      1) Pre-operational and operational sanitation operating procedures were not delineated; employees street clothes inadequately covered during exposed product handling; waste receptacles covers were hand operated; dirty saw cord was touching carcasses; carcasses were touching work-stands; deboned product conveyor belt was damaged; knife sterilizer was inoperative in suspect cooler; and a wall in processing area was in poor repair.
      2) Carcasses were contaminated by contacting dirty surfaces of an elevated platform's protective fence; trimming at final rail was not being performed; incidentally dropped meat was being insanitarily handled, and a carcass retrieved off the floor was not properly trimmed; and the fecal and hair contamination was not being properly trimmed after the final rail inspection.

   b) Establishment 10
      1) Exposed product conveyor belt was damaged; insanitary product handling and inadequate protection against work-stands touching carcasses; and carcasses were contaminated with grease/lubricant in the holding cooler.
      2) Employees were washing hands in dirty water in slaughter area, and carcass-splitting saw was not sanitized after repair.
3. Intra-laboratory check samples for residue and microbiological analyses were inadequate.

4. Species identification testing was not being done.

The Croatian inspection system officials stated that corrective measures had been initiated to prevent the recurrence of deficiencies noted during the previous FSIS audit in November 1999. However, this audit revealed inconsistencies in the HACCP plan and its implementation, lack of evaluation criteria for sponging method for *E. coli* testing, lack of procedures for incidentally dropped carcasses or meat, and failure to conduct species identification testing were still noted.

During January to October 31, 2000, Croatia exported 1,166,880 pounds of cured/canned pork (ham and shoulders), cooked/canned beef, pasteurized canned hams and picnics, and canned varied combination product to the United States. At the U.S. port of entry on reinspection there was no rejection.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with the Croatian national meat inspection officials at Zagreb headquarters to discuss oversight programs and practices, including enforcement activities. The second part entailed on-site audit of establishments 10 and 139 certified for export to U.S. The third part was visits to and review of records maintained at the national headquarters, at the District veterinary health control stations, and auditing of operations and documents in Croatian Institute for Veterinary Medicine (residue and microbiological testing departments), Zagreb, and two regional laboratories located in Rijeka and Krizevci. The fourth part included a visit to a livestock farm to verify animal husbandry practices including proper use and monitoring/control of antibiotics, drugs, and other regulated chemicals or compounds.

Croatia's inspection program effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of HACCP systems, and the *E. coli*, *Salmonella* species and *Listeria monocytogenes* testing program, and (5) compliance enforcement controls, including the testing program for species identification.

Emphasis was placed on verification of information provided by Croatia in response to FSIS questionnaire on 'Residue Control and Testing Program, which included laboratory testing, intra- and inter-agency legislation and regulatory authority, and compliance enforcement.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Croatia has an effective national animal health and residue control programs.

At the time of audit, both U.S.-certified establishments (10 and 139) were acceptable. However, inconsistencies were noted in PR/HACCP plan and its implementation. These included, (1) not conducting statistical analysis, and establishing evaluation criteria for *E. coli* (sponging method) results, (2) not meeting requirements for ready-to-eat product testing for *Listeria monocytogenes*, (3) not conducting product pre-shipment review, (4) not reassessing the HACCP plans, (5) not developing sanitary handling/re-conditioning procedures to protect incidentally dropped meat, and (6) inadequate PR/HACCP training or comprehension of establishment and official inspectors.

Carcasses were branded with green ink in Establishment 10.

Species identification monitoring was not being done.

Entrance Meeting

An entrance meeting was held at the Croatian Ministry of Agriculture and Forestry, Veterinary Administration headquarters in Zagreb on December 5, 2000. The meeting was attended by attended by Dr. Mate Brstilo, Assistant to the Minister Director, Chief Veterinary Officer, Dr. Duro Majurdzic Head Veterinary Public Health Department (meat inspection), Dr. Dr. Nevenka Gašparac, Senior State (Federal) Veterinary Officer for meat and meat product inspection, Dr. Anðelco Gašparac, Head Veterinary Inspection Department, Professor Dr. Ivica Boban, national residues program, Dr. M. Ghias Mughal, Branch Chief, FSIS, International Audit Staff, official interpreter, and Dr. Hussain Magsi, FSIS, International Audit Staff Officer.

Following subjects were discussed:

1. Audit itinerary and travel arrangements.
2. Use of nutritional or geographic claim labels.
3. SSOPs, HACCP, *E. coli*, *Salmonella* spp., and *Listeria monocytogenes* testing.
4. National residue control program, and verification of Croatia's response to FSIS questionnaire on national residue monitoring and control program.
5. FSIS policy on 'listing and delisting' of establishments.
6. Compliance enforcement.

Headquarters Audit

There had been no organizational changes in Croatia's meat inspection systems.

To gain an accurate overview of the effectiveness of inspection controls, FSIS auditor requested that the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements lead the audits of the individual establishments. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditors conducted a review of the inspection system documents that included:

- Organizational structure of Animal Health and Veterinary Public Health Department.
- New initiatives and regulatory changes (Act, regulations, and policy).
- Internal audit/monthly supervisory reports.
- Food safety initiatives such as Sanitation standards and operating procedures (SSOPs), pathogen reduction (PR) for generic *E. coli* testing, *Salmonella* species, and *Listeria monocytogenes* testing, and Hazard Analysis and Critical Control Point (HACCP).
- Performance standards for sanitation, facilities, and equipment.
- Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
- Epidemiology and zoonotic status and trends in Croatia including control of products from livestock disease conditions.
- National residue monitoring and control program.
- Livestock husbandry practices, including use of drugs and chemical and feed additives.
- Compliance enforcement.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Croatian to export meat product to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel. All U.S.-certified establishments are provided continuous inspection.

The Croatian Veterinary Service is vertically structured in the order - Ministry of Agriculture and Forestry's Veterinary Directorate, five State (Federal) Veterinary Institutions for clinical support, laboratory diagnosis and food control testing, and 120 groups of contracted veterinarians for veterinary health and clinical veterinary health support to the public, and 21 county public health and veterinary health control stations. The Veterinary Directorate administers inspection system activities through five departments:

- Animal Health Protection
- Hygiene of Products of Animal Origin and for Veterinary Public Health
- Veterinary Inspection
- Border Veterinary Inspection
- Administration

In the Republic of Croatia there are over 730 meat and poultry establishments. The Directorate employs about 2,239 veterinarians in government headquarters; laboratories, universities, private practitioners, and 672 animal health assistants, usually with 2-3 years of training assist them. The inspection system supervises activities of 296 organizations, 1,212 establishments for slaughter, food processing, animal treatment, and storage of product, 103 establishments for animal feed production, and 44 border crossing inspection.

The 21 District/County Veterinary Inspection offices employ 86 country veterinary inspectors, and 547 authorized veterinarians. They are employed in four Regional Veterinary laboratories in Križevci, Rijeka, Split and Vinkovci, and Poultry Center in Zagreb. These laboratories in conjunction with Central Veterinary Diagnosis Laboratory in Zagreb are responsible for diagnostics, food hygiene, chemical and animal feed analysis activities, providing clinical assistance to the public, and conduct federally planned monitoring/sampling, and conducting compliance enforcement investigations. The Central Veterinary Laboratory through the Veterinary directorate coordinates animal health diagnosis, and analysis for residues and animal feeds, and provides analytical confirmation and specialty support to 21 Counties/districts.

The Croatian Veterinary Institute is comprised of 12 diagnostic/analytical departments: pathology, bacteriology, virology, parasitology, immunology, mastitis, foodstuffs hygiene, animal feed hygiene and feeding, chemistry, determination of residues, pharmacology, and zoo-hygiene. The Poultry Center is comprised of six departments: pathology, bacteriology, virology, mycology and mycotoxicology, animal feed, and biotechnology.

There are 44 Border Inspection points port of entry to control movement import and export of products and livestock at the Slovenia, Hungary, Yugoslavia, Bosnia and Herzegovina border crossings, seaports, airports, and mail system.

Establishment Audits

Establishments 10 and 139 were certified to prepare and export meat products to the United States. Both were on-site audited, and were determined acceptable. With the exception of deficiencies discussed in the report, the inspection and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

The auditors visited Croatian Veterinary Institute (CVI) and its associated microbiology and residue control laboratories in Zagreb, and Regional Veterinary Laboratories in Krizivci and Rijeka. During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories
2. Inter-laboratory quality assurance procedures, including sample handling
3. Methodology

The CVI is a scientific-research and diagnostic institution. It manages five regional laboratories – Veterinary Institute in Split, Rijeka, Vinkovci, Krizevci, and Poultry Center in Zagreb. The principal mission includes animal health protection, jurisdiction over and control of domestic and international livestock movement, product of animal origin, animal feed and veterinary drugs. The research activity includes aspects of broad veterinary issues, animal husbandry, human health safety/food control and testing and environmental protection.

The responsible officials discussed biologics and animal drugs approval, implementation, monitoring and testing of samples for authorized biologics and medicaments, manufacturing and marketing of animal feeds, and control by District/County Animal Health and Food Control Stations. The laboratory analytical results were made available for verification.

The regional laboratories were well equipped and staffed with competent and qualified staff. These labs routinely analyze samples for microorganisms such as *E. coli, Salmonella* species, total plate counts, etc., food and meat products, food additives, animal feed stuffs and supplements, chlorinated hydrocarbons, trace elements, aflotoxins, mycotoxins, and microbiological and physico-chemical analysis of water. The Rijeka laboratory also handled marine fauna microbiological testing. The Rijeka laboratory lacked adequate personnel, equipment and facilities to carry out a vast sampling program, computerized tabulations and maintaining the record keeping instruments, and needed upgrading of some of the analytical equipment.

During a visit to a District/Country Veterinary Office, and a visit to a swine breeding farm, and an animal feed facility located in Dubrovnik, Zagreb county, the auditors were also briefed on the national system on clinical veterinary health public support, monitoring of federal disease control, sampling for food control monitoring, national identification of livestock, monitoring and control of feed additives and drugs, and residue withdrawal and guarantees, and animal health monitoring and medicaments use control programs. The discussions were candid, professionally sound and impressive, records were made available for verifications.

The auditor determined that official monitoring and control systems were in place for sampling procedures, analytical procedures, quality assurance procedures, and review procedures. The analytical methods used were standard, or internationally validated. Deficiency noted during the previous FSIS audit in November 1999 on intra-laboratory check samples frequency had been corrected.

Establishment Operations by Establishment Number

The following operations were being conducted in U.S.-certified:

Establishment 10 – beef and pork slaughter, curing/smoking, cooking and canning
Establishment 39 - beef and pork slaughter, curing/smoking, cooking and canning

SANITATION CONTROLS

Based on the on-site audits of establishments, Croatia's inspection system had controls in place for water potability records; chlorination procedures, back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest monitoring and control; temperature control; lighting; work space; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product storage.

However, procedures for sanitary handling and re-conditioning of incidentally dropped meat were not available in either establishment (Ests. 10 and 139).

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

No variances were noted during the audit.

ANIMAL DISEASE CONTROLS

Croatia's appears to have a well-organized and nationwide coordinated veterinary health and meat inspection system. The controls were in place to ensure adequate animal identification, antemortem and postmortem inspection procedures, carcass and parts disposition, and procedures for sanitary handling of product. The auditor audited official documents and visited the following program areas to reach this conclusion.

Croatian on-going national disease control programs include vaccination against hog cholera, tuberculosis and brucellosis testing of cattle and swine, and rabies vaccination of dogs and cats.

Croatia is free from List A diseases: Foot and Mouth, rinderpest, sheep and goat pox, Newcastle disease, and hog cholera. Diseases such as swine vesicular disease, vesicular stomatitis, Pestes des petis ruminant, contagious bovine pleuropneumonia, lumpy skin disease, Rift Valley fever, bluetongue, and African swine fever have never been recorded. Other disease conditions, such as echinococcosis, leptospirosis, rabies, paratuberculosis, bovine babesiosis, brucellosis (except in bovines), tuberculosis (bovine and porcine), cysticercosis, enzootic bovine leukosis, malignant catarrhal fever, trichinosis, swine reproductive and respiratory syndrome exist in variable intensity. It was determined that livestock husbandry practices, and the disease control program in Croatia were effective

According to Croatian Institute for Public Health, Zagreb, the cases of animal disease origin (zoonosis) in human population reported during 1999 included echinococcosis (17), leptospirosis (131), Q fever (20), bovine cysticercosis (3), trichinellosis (258), and salmonella infection (4,121).

U.S. Animal Plant and Health Inspection Service (APHIS) prohibits the use of beef product of Croatian origin in preparation of beef product intended for U.S. market. Croatia imports beef from Australia for preparation of U.S. export product. *Bovine spongiform encephalopathy* has not been recorded in Croatia.

Animal Identification

Identification (ear tagging/marking) of cattle, swine, sheep, goats, and canines is mandatory. Identification ear tags are issued by and the records maintained by Center for Reproduction in Livestock Breeding of Croatia.

Croatia has an effective and traceable livestock identification system.

RESIDUE CONTROLS

The auditors conducted an in-depth audit of Croatia's national residue control program to verify information provided by Hungarian Government in February 2000 in response to an FSIS questionnaire using a checklist on "Criteria for Assessing the Adequacy of the Residue Control Program for Meat, Poultry, and Egg Products". The criteria used for assessing the adequacy includes verification of information on the background, organization and legal authority, residue plan, residue plan operations, monitoring laboratories, and compliance and enforcement.

Discussions were held with responsible officials for animal Health and Food Control in Zagreb, and other officials associated with national residue control and monitoring program. The discussions focused on (1) identifying and evaluating drugs, pesticides and other chemical compounds of concern by slaughter class and/or egg product, (2) capability to analyze compounds of concern reliability, (3) appropriate regulatory follow-up of reports of violative tissue residues in meat, poultry and egg product, (4) collection, analysis, and reporting of these activities, and (4) anticipated testing plan to analyze compounds of concern for reliability for specific slaughter classes and/or egg products for a specified time period.

The auditor also visited a private livestock farm located in Zagreb County, discussed husbandry and animal health practices with responsible County Veterinary officials. The observations and records review indicated that sufficient controls existed for inventories and authorized acquisition/use of veterinary drugs and supplemental compounds/feed additives, and withdrawal time before slaughtering.

The auditors visited Croatian Veterinary Institute (CVI) in Zagreb, and audited residues and microbiological analytical results. CVI is comprised of laboratories for analyses of trace elements, pesticides, and veterinary drugs. All FSIS required compounds including carbadox and clenbuerol were being tested.

The auditor determined that Croatia had an effective residue control program and met U.S. requirements.

SLAUGHTER/PROCESSING CONTROLS

The Croatian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition; humane slaughter; postmortem inspection procedures; postmortem disposition; restricted product control; pre-boning trim, boneless meat inspection; ingredient identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules; processing equipment and records; empty inspection and filling procedures; container closure examination; post-processing handling; processing defect action-plant; and processing control-inspection.

HACCP Implementation

The establishments approved to export meat products to the U.S. were required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

In both establishments, official veterinary inspectors and establishment PR/HACCP responsible employees had no formal training. The reassessment of HACCP plans had also not been performed.

Pre-shipment verification reviews were not being performed. The establishment considered *Listeria monocytogenes* as a hazard likely to occur in ready-to-eat product, but had not developed and implemented HACCP requirements.

Testing for generic *E. coli*

Croatia has adopted the FSIS regulatory requirements for *E. coli* testing.

Establishments 10 and 139 were required to meet basic FSIS regulatory requirements for *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The sponge-sampling method was used, but the results of the tests were being recorded on a process control chart according to excision evaluation method. This deficiency was also noted during previous FSIS audit.

ENFORCEMENT CONTROLS

Inspection System Controls

The establishments systems conduct boneless meat reinspection, shipment security, including shipment between establishments, and the prevention of commingling of product intended for export to the United States with domestic product.

Residue Controls

Croatia's national residue testing plan for FY 2000 was being followed and was on schedule. The Croatian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures, storage and use of chemicals.

Three samples were found to exceed action level for cadmium during the year. The inspection system investigated the incidences, collected additional samples from the suspect herds/farms and animal feed and water, but found them negative.

Testing for *Salmonella* species

Establishments 10 and 139 were required to meet the basic FSIS regulatory requirements for *Salmonella* species testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* species-testing program was audited and found to meet the FSIS determined equivalence. The inspection service collected samples. In case of positive case, product is identified, re-called if available, and confiscated for further action. Future shipments are withheld subject to laboratory analyses clearance. Investigation is conducted to determine root-cause(s) of product adulteration.

Testing for *Listeria monocytogenes*

The Bacteriology Laboratory at the Croatian Veterinary Institute routinely performed *Listeria monocytogenes* monitoring of the fresh beef matrices (brain, kidney, liver, spleen and muscle), pork fresh matrices (brain, kidneys, livers, muscle, lungs and lymph nodes), and ready-to-eat canned product. The Veterinary Directorate determined the frequency of sampling by official inspectors, and action for violation. The laboratory analyzed 21 fresh beef samples, 21 fresh pork samples, 48 canned product samples during CY 2000. All samples were negative.

However, the establishment considered *Listeria* a hazard likely to occur, but had not included in its HACCP plan.

Carcass Branding Ink

Carcasses in Establishment 10 were being branded with green ink.

Species Verification Testing

At the time of this audit, Croatia was not exempt from species verification-testing requirement. However, the verification testing was not being done. Both establishments deboned and processed beef and pork products.

It was learned that there were no species identification testing provisions in the Croatian Law. The testing was conducted in Croatian Veterinary Institute only when requested by the in-plant inspectors. It was stated that inspection service had discussed this issue with FSIS auditor during November 1999 audit, and had agreed to develop testing procedures for continued monitoring. The option had been evaluated, and the testing procedure to be used would be started very shortly.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

Responsible State/Federal Senior Veterinary Officers conducted U.S.-certified establishment reviews infrequently, some time monthly and some time every other month. The supervisory Country Veterinary Officers also performed in-depth establishment audits from time to time.

Enforcement Activities

Each County's field staff officers provide livestock transportation certificates, verify withdrawal of drugs before slaughter, monitor and control additives and regulated drugs administration to the livestock and use in feed stuffs, monitor rendering facilities, and investigate violations of residue and other regulatory requirement. Violations are reported to police for legal action, and fines. The compliance enforcement action pertaining to product confiscation, fines, and imprisonment are legislated. It was stated that actions are taken when laws are transgressed.

FSIS Quarterly Regulation and Enforcement Report (April - June 2000) were presented to the meat inspection officials. The government was requested during the entrance meeting to provide compliance enforcement information.

Dr. Nevenka Gašparac provided an excerpt and tabulated information on compliance enforcement activity in Croatia during FY-2000, and was reviewed.

During 1999, 3,207 violations and 12 criminal cases were recorded for breach of veterinary inspection system requirements for food product of animal origin. In 2000, according to the provisions of relevant Croatian national laws and regulations (*Report on the 'Work of authorized veterinarians according to the District)*, 9,968 cases for violation of inspection laws had been recorded and investigated. Of these 493 cases were recommended for regulatory punitive action, and one for criminal action.

The authorized veterinarians also rendered 6,516 verbal and 3,572 written warnings and took appropriate regulatory action for violations of the inspection requirements. In order to assure safety of products of animal origin and animal feeds, 41,009 samples were collected for routine analysis, and 489 samples for confirmatory or surveillance purposes. No violations were found during 2000. The violators could be fined according to severity of criminal offense and amount of product involved. The fine range from Croatian Kuna 7,000 to 20,000, and up to one-year incarceration.

Exit Meeting

An exit meeting was conducted in Zagreb on December 12, 2000, and was attended by Drs. Mate Brstilo, Duro Majurdzic, Andelco Gašparac, Nevenka Gašparac, M. Ghias Mughal, Hussain Magsi, and Ms. Branka Rajkovic (professional interpreter).

The auditors discussed the findings and observations made during the audit. These specifically included deficiencies for HACCP, *Listeria* as a hazard likely to occur in ready-to-eat product, pre-shipment verification, *E. coli* evaluation criteria and charting of results, pre-shipment verification, HACCP plans re-assessment, HACCP training, and species identification testing.

Dr. Brstilo appreciated FSIS auditor's effort in explaining the PR/HACCP philosophy, rules, and discussed difficulties in interpretation and preparation of plans, and understanding of the implementation requirements of PR/HACCP rule. He also stated that under a 'World Bank Grant', they were going to send five supervisory officials in February 2001, and 10 County and in-plant veterinary officers to College Station, Texas for HACCP training program offered by the 'HACCP Alliance Group'.

The inspection officials stated that:

1. Copy of FSIS previous audit in November 1999 was not received. Therefore certain FSIS's PR/HACCP requirements were not fully understood. However, official guidelines had been issued to the establishments and the field staff to resolve inconsistencies in the PR/HACCP plan for implementation for reassessment, pre-shipment verification, evaluation criteria development for *E. coli* testing, and *Listeria* testing for ready-to-eat product.
2. Immediate corrective measures had been taken to develop and implement written procedures to preclude contamination of incidentally dropped meat.

3. Croatian law required food grade ink irrespective of color. Therefore use of green ink was allowed in Establishment 10. However, use of green ink had been discontinued immediately following the audit.
4. The testing would be started immediately.

CONCLUSION

The overall establishment system was determined to be equivalent to that which FSIS requires in domestic establishments. However, inconsistencies in PR/HACCP plans and their implementation existed, which were being addressed by the inspection service. Responsible personnel had been scheduled for formal HACCP training in Texas. It was stated that species identification analysis, branding ink, and re-conditioning of incidentally contaminated product had been corrected.

The national animal health and residue control programs were effective and met U.S. requirements.

Croatia has an extensive network of regulatory compliance enforcement systems at local, county and national level. The deficiencies encountered during this audit were adequately addressed to the auditor's satisfaction.

(signed)Hussain Magsi, DVM, MS
Hussain Magsi, DVM, MS
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for generic *E. coli* testing
D. Data collection instrument for *Salmonella* species testing
E. Laboratory audit forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available).
H. FSIS Response(s) to Foreign Country Comments (when it becomes available).

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1.Written program addressed	2. Pre-op sanitation addressed	3. Operational sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6.Responsible individual identified	7.Documenta-tion done daily	8. Dated and signed
10	√	√	√	√	√	√	√	√
139	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. No	1.Flow diagram	2.Hazard analysis done	3. All hazards identi-fied	4. Use and users included .	5. Plan for each hazard	6. CCPs for all hazards	7.Monit. critical limits, and freq. specified	8.Correc-tive actions described	9. Plan valida-ted	10. Adeq. Verific. Proc.	11. Ade-quacy of docume-entation.	12. Dated and signed
10	√	√	*	√	√	√	√	√	√	**	√	√
139	√	√	*	√	√	√	√	√	√	**	√	√

* *Listeria monocytogenes* as hazard likely to occur was analyzed, but the requirements were not being met.
** Reassessment of HACCP plans was not performed, and pre-shipment verification was not being done.

Attachment C

Data collection instruments for *E. coli* testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

Est. No.	*1. Written procedure	2. Sample collector designated	3.Sampling location given	4.Predomi-nant spp. sampled	5.Sampling at required frequency	6.Proper site or method	7.Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
10	*	√	√	√	√	√	√	√	√	*
139	*	√	√	√	√	√	√	√	√	*

*The sponge-sampling method is used, but the results of the tests are being recorded on a process control chart showing the most recent test results according to excision evaluation method.

Attachment D

Data Collection instruments for *Salmonella* spp. Testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* species testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

*The results of these evaluations were as follows:

Est. No.	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper production	7.Violative Est. stop operations
10	√	√	√	√	√	*
139	√	√	√	√	√	*

* Product is identified, re-called if available, and confiscated for further action. Future shipment is withheld subject to laboratory analyses clearance.